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10/598,073

08/17/2006

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

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1645

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/598,073 | Applicant(s) FERNANDEZ-SALAS ET AL. | |
| | Examiner GINNY PORTNER | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/17/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-78 are pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-33, drawn to a plurality of methods of detecting botulinum toxin activity.

Group II, claim(s) 34-36, drawn to methods of reducing botulinum toxin activity in a human by administering a molecule.

Group III, claim(s) 37-76, drawn to methods of screening for inhibitors of botulinum toxin activity.

Group IV, claim(s) 77-78, drawn to business method.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Keller et al (1999) describe the special technical feature in the first appearing invention directed to a method of detecting botulinum toxin type A activity relative to a control cell, wherein the difference in activity is indicative of botulinum toxin type A activity. The cell is a spinal cord cell culture that comprises a neuronal component (see page 138, sections 2.3, 2.4, 2.5, 3.1 and Figure 1, the spinal cord cell culture presenting a wild type naturally occurring variant receptor for botulinum toxin type A which is encompassed by Applicant's definition at Specification [0035], the exogenous receptor binding to BoNT/A complex (see section 2.5, page 138) which resulted in transport of BoNT/A and a showing of a difference in activity (see Figure 1). A Lack of Unity of invention exists because Keller et al describes the first appearing special technical feature; the first appearing invention not making a contribution over the prior art.

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3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. The claimed species are deemed to correspond to the following claims; the species listed below in the following manner:

Group I:

Claim 2, cell transiently contains an exogenous receptor for BoNT/A

Claim 3, cell stably contains an exogenous receptor for BoNT/A

Claim 4, cell contains a mammalian receptor for BoNT/A

Claim 5, cell contains a human receptor for BoNT/A

Claim 6, cell contains a bovine receptor for BoNT/A

Claim 7, cell contains a mouse receptor for BoNT/A

Claim 8, cell contains a rat receptor for BoNT/A

Claim 9, cell contains a bird receptor for BoNT/A

Claim 10, cell contains a chicken receptor for BoNT/A

Claim 11, cell contains an amphibian receptor for BoNT/A

Claim 12, cell contains a frog receptor for BoNT/A

Claim 13, cell contains a newt receptor for BoNT/A

Claim 14, cell contains a fish receptor for BoNT/A

Claim 15, cell contains a zebra fish receptor for BoNT/A

Claims 23-27 non-neuronal cells that comprise a BoNT/A receptor.

Group III:

Claim 41 cell transiently contains an exogenous receptor for BoNT/A

Claim 42, cell stably contains an exogenous receptor for BoNT/A

Claim 43, cell contains a mammalian receptor for BoNT/A

Claim 44, cell contains a human receptor for BoNT/A

Claim 45, cell contains a bovine receptor for BoNT/A

Claim 46, cell contains a mouse receptor for BoNT/A

Claim 47, cell contains a rat receptor for BoNT/A

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Claim 48, cell contains a bird receptor for BoNT/A

Claim 49, cell contains a chicken receptor for BoNT/A

Claim 50, cell contains an amphibian receptor for BoNT/A

Claim 51, cell contains a frog receptor for BoNT/A

Claim 52, contains a newt receptor or BoNT/A

Claim 53, contains a fish receptor or BoNT/A

Claim 54 contains a zebra fish receptor or BoNT/A

Claims 62-66 non-neuronal cells that comprise a BoNT/A receptor.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP

§ 809.02(a).

The following claim(s) are generic: Group I, claim 1 and Group III, claim 37.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each species of invention evidences a different chemical structural, function and biological effect. The first appearing invention does not define a special technical feature that makes a contribution over the prior art. The claimed inventions are not so linked as to evidence Unity of invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

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103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
June 16, 2008

/Mark Navarro/
Primary Examiner, Art Unit 1645